OPERATOR'S GUIDE

Volumetric Infusion Pump

OPTIMA PT

Introduction

Great care has been taken in the design and manufacture of the **Optima PT**, a volumetric infusion device.

The configuration flexibility of the **Optima PT** provides overall improvement in the working conditions of medical teams, thus increasing patient safety.

The use of this material requires great care. The user must be able to handle the instrument properly and must know how to fully operate.

Please read the operator's guide carefully before putting the device into use.

Table of contents

1. **Operations for use** 2
2. **Advanced functions** 4
3. **Optima PT - Internal safety features** 7
4. **Optima PT - Performances** 10
5. **Optima PT - Technical characteristics** 11
6. **Configuration menu** 13
7. **Precautions to be taken** 15
8. **Maintenance recommendations** 16
9. **RS 232 connection** 17
10. **Nurse call connection** 17
11. **Drip sensor** 17
12. **Function with the internal battery** 17
13. **Accessories** 18
14. **Disposable** 19
15. **Conditions of guarantee** 20
16. **Useful addresses** 24

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1. Operations for use

1.1. Installation of the Optima PT

Special attention must be paid to the stability of the Optima PT.

The Optima PT can be used on mains or battery .

Note: connect device to mains as often as possible to recharge batteries.

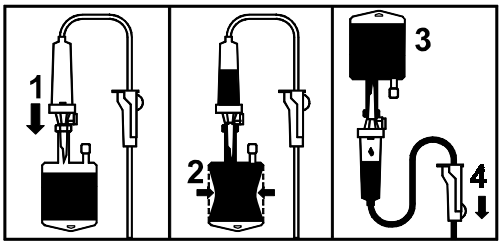
1. **Connect the power supply cord to the pump and to the mains source. The mains power indicator lights up .**
2. **Quick check : see protocol page 9. This test is recommended or mandatory (in case of in-forced law): it allows a complete alarms & safety features check. It is recommended before use or when the device has not been used for a long time.**

1.2. Tubing set installation

1. **Choose from the range of infusion sets proposed on page 18, the one that best suits the protocol you are using. The infusion set must be in normal temperature conditions: +18°/+30°C.**
2. **Prepare the solution container (bag/bottle) with its associated infusion line according to the standard infusion procedures. Important: the solution container must be in normal temperature conditions: +18°/+30°C.**

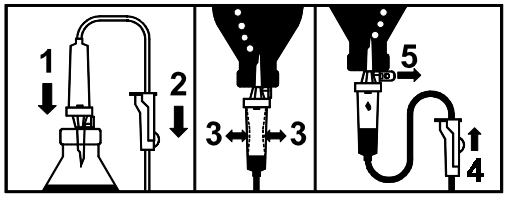
1.2.1. Purge of the set used with a bag

1. Introduce the spike right down into the bag (roller clamp open – air inlet closed).
2. Press the bag in order to remove the air, and fill the drip chamber up to 1/2 of its capacity.
3. Hang the bag upside down, and let the liquid flow into the set.
4. Once the set is completely primed, close the roller clamp and check absence of air bubble.



1.2.2. Purge of the set used with a bottle

1. Introduce the spike right down into the bottle (roller clamp open, air inlet closed)
2. Close the roller clamp.
3. Hang the bottle upside down then press the drip chamber in order to fill it till ~ 1/2 of its capacity.
4. Open the roller clamp.
5. Open the air inlet, and let the liquid flow into the set.



6. Once the set is primed, close the roller clamp and check absence of air bubble.

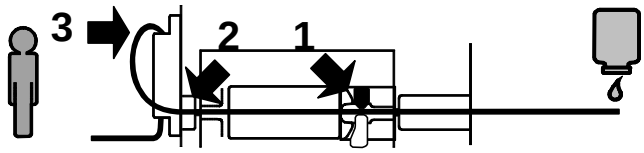
1.2.3. Switching on and installation of the infusion set

Open the pump door by lifting the door handle. The pump automatically switches on when connected to mains (if configurated). If not, press .

Auto-test checks functionality of the pump. Make sure that all LED & buzzers are activated. Warning may be displayed at that time. Please refer to the warning section.

Check the type of set displayed is the one you are using.

1. Lift pump clamp upward and insert tube as indicated in the drawing.

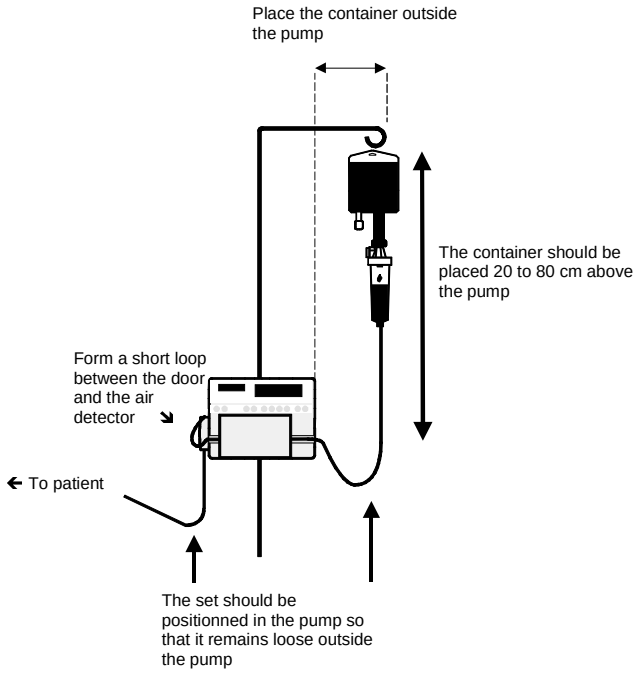


2. Insert the tube into left set guide so that the tube is held, in straight position, on the pumping membrane.
3. Insert the tube into air detector by forming a loop.
4. Close the door by pushing the door handle.

1.2.4. Drip sensor

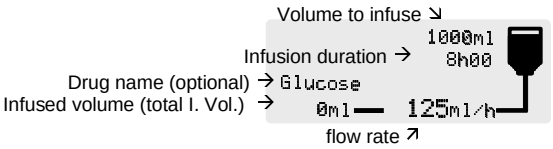
1. Connect the drop detector plug of to the connection socket on the back of the pump.
2. Connect the drop detector to the drip chamber.

Important: control the right positioning of the drip chamber and check there are no drops on the drip chamber walls.


Place the container outside the pump
The container should be placed 20 to 80 cm above the pump
Form a short loop between the door and the air detector
To patient
The set should be positionned in the pump so that it remains loose outside the pump

1.3. Infusion setting

1.3.1. Setting with Volume / Time / Rate



1. Select the volume to infuse with ⏫🔼🔽⏬, then confirm and shift to next item with ⏎.

   Caution : the volume set must be the closest possible to the actual volume of the container. All added or removed volumes must be taken into account, including the volumes of fluids contained in the set and lost during priming which must be removed from the volume to infuse (~ 25 ml).

2. Select the infusion duration with ⏫🔼🔽⏬, then confirm and shift to next item with ⏎.
3. Select the flow rate with ⏫🔼🔽⏬, then confirm and shift to next item with ⏎. The infusion duration is automatically calculated and readjusted according to displayed flow rate.
4. Check the infused volume. Erase it if desired with ⏫🔼🔽⏬.
5. Open the roller clamp. Check there is no free flow nor air remaining inside the infusion line.
6. Connect set to IV Infusion site according to good clinical practices.
7. Press START to start infusion.

Note:

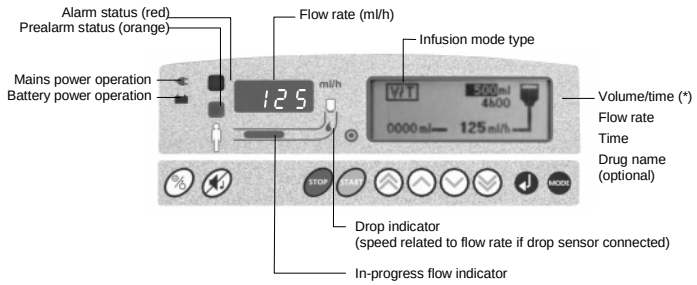
- When the optional drip sensor is used, the volume to infuse can be set at zero. The infusion therefore automatically stops when drops are no longer detected, thus enabling to fully empty the container.
- When using secondary mode, this setting is stored as primary mode.

1.3.2. Setting with flow rate only

This setting mode is available only if the drop detector is used.

1. Select the flow rate with ⏫🔼🔽⏬.
2. Open the roller clamp. Check there is no free flow nor air remaining inside the infusion line.
3. Connect set to IV Infusion site according to good clinical practices.
4. Press START to start infusion.

1.4. Information during infusion



(*) In alternance with infused volume : total volume (Total IV) or partial volume (Partial IV).

Total volume is displayed when the same drug has been infused and the same infusion mode has been used.

Partial volume is displayed when different drugs have been infused or when different modes have been used.

1.5. Hold of infusion

Press STOP. An audible alarm triggers after 2 minutes.

1.6. Change of container

1. Press STOP to hold infusion.
2. Close roller clamp.
3. Disconnect set from the old container.
4. Connect set to new container according to good clinical practices.
5. Check fluid level in drip chamber (around half of its capacity) Prime the line if some air remains inside.
6. Program new infusion parameters : flow rate, volume, …
7. Open roller clamp.
8. Start infusion.

1.7. Change of set

1. Press STOP to hold infusion.
2. Close roller clamp.
3. Disconnect set from container.
4. Disconnect set from IV device according to usual clinical practices.
5. Open the door and remove set from pump.
6. Select and prepare new set as indicated above.
7. Program and start infusion as indicated above.

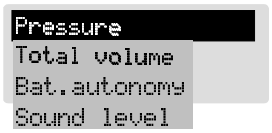
1.8. Turning off the Optima PT

Press STOP, then 🔘 for more than 2 seconds.

2. Advanced functions

When activated in the configuration menu, all advanced functions can be reached by pressing MODE.

Then, press ⏫🔼🔽⏬ to reach required item and ↵ to enter desired screen.



Note: Upon pump status (stop or infusion), some functions may not be available. Example: loading dose is not available after infusion start.

2.1. Pressure monitoring and setting

1. Press MODE, then ↵.

↙ Line disconnection / Drop in pressure alarm
← Pressure alarm threshold
← Infusion pressure
↖ Dynamic Pressure System
Pressure increase control

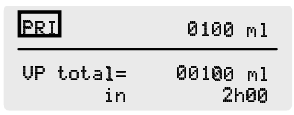
2. Press ↵ to select item.
3. Press ⏫🔼🔽⏬ to select value.
4. Return to main screen by pressing MODE.

2.2. Total volume / Infused volume by mode

1. Press MODE:

2. Press ↵ to select “Total Volume”.
3. Using the ↵ key, the infused volumes of the different modes (Secondary, Primary, Ramp up / down, Sequential) are displayed.
4. To clear the total infused volume, the infusion should be on hold. Switch to the total volume screen and use the 🔽 key to clear (use the 🔼 key to restore).

   When total volume is cleared, all infused volumes of the different modes are also cleared.



5. Confirm by pressing ↵. Then, press MODE to escape.

2.3. Battery charge level

The present battery charge level can be reached by pressing either MODE or 🔕:

← Average battery life at current flow rate
← battery charge indication

See paragraph 9 for operation with battery.

2.4. Bolus

1. Access with the MODE key and enter the bolus function with ↵.

2. If necessary, select the volume of bolus to infuse with ⏫🔼🔽⏬. Then, confirm and shift to next item with ↵.
3. Select the bolus duration with ⏫🔼🔽⏬. The bolus rate is automatically calculated.
4. Select the flow rate bolus with ⏫🔼🔽⏬. The bolus duration is automatically calculated and readjusted according to displayed flow rate.
5. Check bolus parameters and start bolus infusion by pressing START.
6. After the bolus has been delivered, a short beep is emitted. The pump automatically resumes its initial status (stand-by or infusion) and the bolus programming parameters are stored.
   If the bolus is interrupted, the remaining bolus volume to infuse is kept in memory.

Notes:

- Infused bolus volume is subtracted from remaining volume to infuse.
- For a bolus at infusion start, use loading dose mode.

2.5. Secondary infusion

2.5.1. Definition

This programming mode enables the infusion of a secondary line placed above, automatically followed by the infusion of a primary line placed below. The parameters of the primary infusion must be previously set.

1. Place the drip sensor on the primary line.
2. Select the secondary volume to infuse with ⏫🔼🔽⏬. Then, confirm and shift to next item with ⏎.
3. Select the secondary infusion duration with ⏫🔼🔽⏬. Then, confirm and shift to next item with ⏎.
4. Select the drug name (optional) with ⏫🔼🔽⏬. Then, confirm and shift to next item with ⏎.
5. Select the flow rate with ⏫🔼🔽⏬. The infusion time is automatically calculated and readjusted according to displayed flow rate.
6. Start secondary infusion by pressing START.
7. After the secondary infusion has been delivered, a short beep is emitted. The pump automatically resumes the primary infusion.

Note that if opening the clamp is forgotten, the drip alarm triggers.

2.5.2. Recommendations in case of secondary infusions

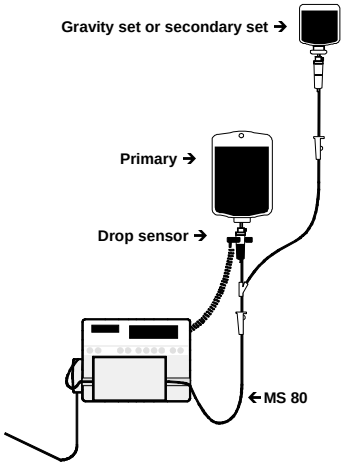
The use of the drop sensor is mandatory. The use of MS80 as primary set is recommended.

The container of the secondary solution must be placed higher than the one of the primary solution.

Setting of the secondary volume to be infused must be equal to the volume of the solution in the secondary container.

One must then take into account the variables such as over volume in container, addition of medicines, etc.

If a volume lower than the real volume is set, the remaining secondary solution will infuse at the primary rate. If, on the contrary, a higher volume is set, part of the primary solution will be infused at the secondary rate.



Note: the set must be equipped with a one way valve to prevent the secondary solution from filling the primary container.

2.6. Programming pause

1. Press STOP twice, or reach programming pause with MODE key.
2. Select pause duration in minutes and hours with ⏫🔼🔽⏬. Confirm with ⏎. After the pause has ended, an auditing signal is emitted.
3. If required, stop the pause by pressing STOP, or START to restart the infusion.

2.7. Key locked/unlocked

1. Access with the MODE key.

2. Select locked or unlocked position with ⏫🔼🔽⏬ and press ⏎.

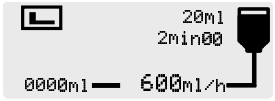
Note: when locked, the infusion parameters cannot be changed.

2.8. Loading dose

This infusion mode enables the delivery of a volume (e.g. loading dose) automatically followed by the delivery of the primary infusion.

The parameters of the primary infusion must be previously set according to paragraph 1.3.

Note that infused loading dose volume is automatically subtracted from primary volume to infuse.



1. Select the volume to infuse with ⏫🔼🔽⏬. Then, confirm and shift to next item with ⏎.
2. Select the infusion duration with ⏫🔼🔽⏬. Then, confirm and shift to next item with ⏎.
3. Select the flow rate with ⏫🔼🔽⏬. The infusion duration is automatically calculated.
4. Start loading dose delivery by pressing START.

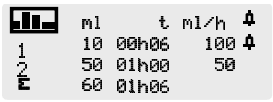
2.9. Ramp up/Ramp down

By setting ramp up and ramp down durations, the pump will automatically increase the flow rate to reach in ten intermediate steps the plateau flow rate and, at the end of the infusion plateau, decrease the flow rate down to zero.

1. Select the volume to infuse with ⏫🔼🔽⏬. Then, confirm and shift to next item with ⏎.
2. Select total infusion duration in minutes with 🔼🔽, in hours with ⏫⏬. The sustaining flow rate is then automatically calculated.
3. Select ramp-up duration in minutes with🔼🔽, in hours with ⏫⏬. Then, confirm and shift to next item with ⏎.
4. Select ramp-down duration in minutes with 🔼🔽, in hours with ⏫⏬. Then, confirm and shift to next item with ⏎.
5. Start infusion by pressing START.

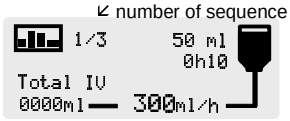
2.10. Sequential programming

From 1 up to 20 infusion sequences can be defined in volume to infuse and rate of infusion. Pause periods (Stop) or KVO periods could also be defined in the sequence program:



1. Select the volume of the first sequence with ⏫🔼🔽⏬. Then, confirm and shift to next item with ⏎.
2. Select the duration of the first sequence with ⏫🔼🔽⏬. Then confirm and shift to next item with ⏎.
3. Select the flow rate with ⏫🔼🔽⏬. The infusion duration is automatically calculated and readjusted according to displayed flow rate. Confirm and shift to next item with ⏎.
4. Activate or de-activate beep at the end of the sequence with ⏫🔼🔽⏬. Then, confirm and shift to next item with ⏎.
5. Select next sequence with 🔽, and shift to next volume to infuse with ⏎.
6. Set new sequence(s) in the same way.
7. End last sequence by selecting “end” as last volume to infuse.
8. Check programming sequences and confirm with START key.

Number of pending sequence / out of total
↙ number of sequence



9. Start sequential infusion by pressing START.

Changes in the sequence program will become active only if the sequences are re-started or have not already been reached. A beep sound could be activated at each end of a sequence.

Notes :

- To modify the ongoing sequence, press STOP, change the ongoing sequence parameters and press START key to validate. The sequential program is not modified.
- If sequence program is modified during sequential infusion, only forthcoming sequences will be modified.

2.11. Micro Infusion Flow Rate

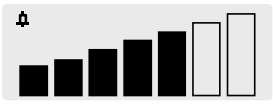
When the micro infusion flow rate is activated (see Configuration menu), a decimal digit is displayed both for flow rate and for volume.

- **Flow rate range** : from 0.1 ml/h to 100 ml/h, 0.1 ml/h increment. In order to insure a high flow rate accuracy, the lower limit is set at 0.5 ml/h (see Precaution to be taken before use page 15). For a setting as of 0.1 ml/h, contact our After-Sales Service Department.
- **Bolus Flow rate range** : from 0.1 ml/h to 300 ml/h, 0.1 ml/h increment from 0.1 to 100 ml/h, 1 ml/h increment above 100 ml/h.
- **Volume limit range for primary infusion** : 0.1 ml to 1000 ml, 0.1 ml increment.
- **Volume limit for secondary infusion** : 0.1 ml to 1000 ml, 0.1 ml increment from 0.1 to 100 ml; 1 ml increment, above 100 ml.

Note: volume is displayed at ± 0.1 ml.

2.12. Sound level

The sound level can be adjusted with the selection keys ⏫🔼🔽⏬.



Press ⏎ to confirm.

3. Optima PT - Internal safety features

Optima PT has a continuous inspection system which functions as soon as the pump is in use. Any internal failure or anomaly detected will be immediately displayed.

Nevertheless, the qualified personnel in your establishment or our After-Sales Department should always be notified of any abnormal function where no specific cause can be found.

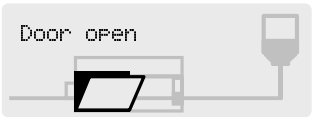
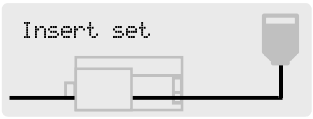
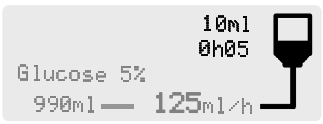
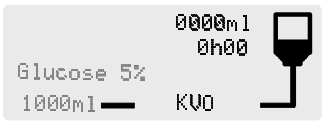
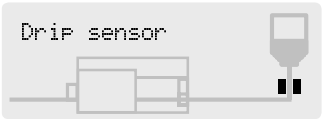
3.1. Optima PT – Alarms, pre-alarms and warnings

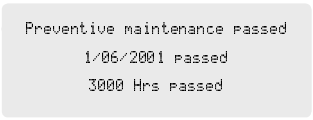
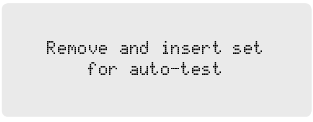
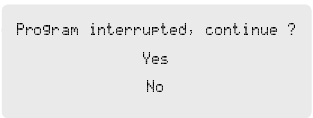
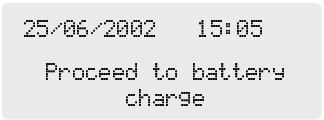
All alarms are displayed with a flashing red light at the left of the front panel and are indicated with an audible signal. The audible signal can be switched off for 2 minutes by pressing .

All pre-alarms are displayed with an orange light flashing on the left side of the front panel.

All alarms are displayed with a red light flashing on the left side of the front panel.

The right LCD display provides explanations about alarms, pre-alarms and warnings :

Message on LCD display	Meaning	Causes	Actions to do
	**Door open alarm.** Infusion stops.	▪ Door is open.	Close the door. Check tube positioning.
	**Set insertion alarm.** Infusion can not be started.	▪ Set mis-positioned.	Check set insertion.
	Air Alarm. Infusion stops.	▪ The volume of air in line is above limit. ▪ Set is not properly inserted in air detector.	Remove air bubble in line by priming set according to facility protocol. Check set positioning in air detector.
	**End of infusion pre-alarm.** Infusion continues.	▪ 5 minutes or 5% volume before volume limit is reached.	Check if remaining volume in container is in accordance with remaining volume to infuse. If needed, prepare container for a new infusion sequence.
	**End of infusion alarm.** Infusion continues in KVO mode.	▪ Volume limit is reached.	If needed, set a new infusion sequence.
	**In case of use with drip sensor only :** **Flow control alarm** Infusion stops.	▪ Empty container. ▪ Roller clamp closed. ▪ Drip sensor is not properly positioned. ▪ Drip sensor has been placed onto the secondary line. ▪ Drip chamber over filled.	Check container. Check roller clamp. Check air-inlet cap (if bottle is used). Check drip sensor positioning. Check fluid level in drip chamber. Check set. Check the fluid temperature.
	In case of use with drip sensor only : **Set positioning** Infusion stops.	▪ Over-flow. ▪ Mispositioning of infusion set.	Open the door and check set positioning. Check drip sensor positioning.
	Downstream occlusion alarm. Infusion stops.	▪ Downstream pressure in line exceeds pressure threshold programmed.	Check infusion line. Check if pressure threshold is set in relation to flow rate.

Message on LCD display	Meaning	Causes	Actions to do
	Upstream occlusion alarm. Infusion stops.	▪ Upstream pressure in line is too low. ▪ Empty bag. ▪ Roller clamp closed. ▪ Air inlet cap is closed (if bottle is used).	Check container. Check roller clamp. Check container height. Check air inlet cap (if bottle is used).
 ● orange (on front panel)	**Occlusion pre alarm.** Infusion continues.	▪ In-line pressure has reached 50 mmHg below pressure threshold.	Check the infusion line. Set proper pressure threshold.
	Pressure drop warning. Infusion continues.	▪ Pressure in line is dropping.	Check downstream luer lock connection.
	Pressure increase warning. Infusion continues.	▪ Pressure in line is increasing.	Check downstream line. Check if pressure threshold is in accordance with flow rate.
   ● orange (on front panel)	**Low battery pre-alarm.** Infusion continues. The pre-alarm is activated at least 30 min before the battery alarm when the battery is properly charged.	▪ Battery life is low.	Connect Optima PT to the mains.
	Discharged battery alarm. Infusion stops. Pump will automatically switch off after 5 minutes.	▪ Battery charge is over.	Connect Optima PT to the mains.
Er10, Er11; Er21 (LED display)	**Motor rotation alarm.** Infusion stops	▪ Control signal failure.	Press STOP to resume the device to normal operation.
Er-- (LED display)	**Technical alarm.** Infusion stops. Pump can not start.	▪ Technical failure.	Note error code and contact the qualified technicians in your establishment or our After-Sales Department.
	**It is time to conduct the preventive maintenance.**	▪ Maintenance date has been reached or total running time is over.	Press START to continue normal operation. Contact Service Department to plan pump servicing in the coming months.
	**The set is in the pump for long time and needs to be removed to control pump functions.**	▪ The pump has been switched on and off with a set installed for more than 24 hours.	Remove the set from air detector and install it again. If this warning persists, contact the qualified technicians of your establishment or our after-sales service.
	**The pump has been turned off while the volume to infuse has not been reached. You can decide to resume the infusion from the point when the pump was turned off or to reset the infusion parameters.**	▪ The pump retains the infusion parameters for more than 6 hours. This is independent of the total infused volume that can be permanently stored.	Select "No" to reset infusion parameters. Select "Yes" to resume the infusion.
	**Set date and time.**	▪ The pump has been out of mains power for a long time.	Set date and time and charge the battery.

3.2. Quick check

This test is recommended or mandatory (in case of in-force law).

It allows a complete alarm and safety features check of the Optima PT (no patient connected).

Serial number (ID/N): ..... Date: ..... / ..... / ..... Department: ..... Name: .....

		Results
1.	**Switch the pump ON, pressing the key, without tube:** **- check buzzer and LEDs test.**	**YES ☐ NO ☐**
2.	**Open the pump door :** **- check message:** door opened	**YES ☐ NO ☐**
3.	**Install set (filled with fluid) without positioning the tube in the air sensor :** **- close the door and check message :** air in line	**YES ☐ NO ☐**
4.	**Insert the tube in the air sensor. The air alarm message disappears.**	**YES ☐ NO ☐**
5.	**Set infusion parameters – 500 ml/h (no patient connected).** **- start infusion.**	
6.	**Clamp the upstream line with the roller clamp:** **- check upstream occlusion alarm (less than 15 seconds).**	**YES ☐ NO ☐**
7.	**Open roller clamp.**	
8.	**Start infusion (500 ml/h) and clamp the downstream line:** **- check occlusion alarm (less than 15 seconds).**	**YES ☐ NO ☐**
9.	**Unclamp the downstream line. Open the door:** **- check that there is no more than 3 drip falling in the drip chamber.**	**YES ☐ NO ☐**

Quick check is OK if answers are "yes" for all items.

4. Optima PT - Performances

4.1. Flow rate available from keyboard selection

From 1 to 1000 ml/h, 1 ml/h increment.

In micro infusion mode: from 0.1 to 100 ml/h, 0.1 ml/h increment.

4.2. Volume limit and volume infused

From 1 to 9999 ml, 1 ml increment, displayed at ± 1 ml.

In micro infusion mode: from 0.1 to 1000 ml, 0.1 ml increment.

4.3. Time limit

From 0h01' to 96h00', 1' increment, displayed at ± 1'.

4.4. Pressure limit threshold

From 100 to 900 mmHg, 50 mmHg increment.

± 75 mmHg, or ± 15%.

4.5. Dynamic Pressure System (DPS)

Pressure increase

Anticipates an occlusion during infusion, recommended for low flow rates when quick occlusion detection is required.

Pressure drop

A pressure drop indication may be a warning of infusion line disconnection.

Can be used to prevent disconnection when a significant pressure is present in the infusion line.

4.6. Air detection

Default setting: 250 µl, detected as a single bubble or cumulated volume air over a period of 15 minutes, from bubble sizes above 50 µl. Resolution of sensor : ~ 10 µl.

These values can be adjusted in ward setting menu (refer to "Ward setting menu" paragraph, page 14).

4.7. Average flow rate accuracy

VS sets PVC type or VS sets PVC free type or MCM 400

- Flow rate accuracy ± 5% first 24 hours.
  ± 10% (*) between 24 and 72 hours.

Fresenius Infudrop Air PD, Codan PVC (Pressure), Braun Intrafix, BD Ohmeda R 87 P:

- Flow rate accuracy ± 10% (**) over period of 24 hours.

These values are given for an intermediate flow rate of 100 ml/h and when the tube type is selected on the device (see technical manual).

(*) A better accuracy, over a long period of time, can be obtained by regularly shifting the tube segment in contact with pumping system every 24 hours.

(**) Tested on one batch. Contact tube's manufacturer for batch dispersion.

4.8. Change set interval

We recommend to change the set after 24 hours and/or 2.5 liters for very tight flow rate accuracy (check local protocols).

We recommend to change the set after 72 hours of use or 7 liters.

4.9. Volume / Time and rate setting

The device operates at the displayed rate. The time entered is readjusted according to the formulae:

$$\textbf{Time} = \frac{\textbf{Volume to infuse}}{\textbf{Rate displayed}}$$

4.10. Response time & bolus release after occlusion alarm according to infusion flow rate for VS tube

Flow rate	Threshold value mmHg	Response time h/min/sec	Bolus ml
1 ml/h	100	< 12'	< 0.1
	300	< 30'	< 0.15
	750	< 1h15'	< 0.25
25 ml/h	100	< 12''	< 0.15
	300	< 45''	< 0.15
	750	< 2'30''	< 0.25
100 ml/h	100	< 6''	< 0.15
	300	< 20''	< 0.15
	750	< 45''	< 0.25

To reduce bolus and occlusion detection delay at low flow rates we recommend you to select the appropriate threshold value according to your needs and the above table.

4.11. Programmed Bolus Infusion

Volume infused accuracy : deducted from tube accuracy versus volume/time programmed, or ± 0.1 ml.

4.12. Ramp up/down mode

Flow rate accuracy : following average flow rate accuracy with recommended set.

4.13. Sequential mode

Flow rate accuracy per sequence: following average flow rate accuracy with recommended set.

4.14. KVO Rate

Activated when the volume to infuse is reached. 3 ml/h for 30 minutes for flow rate selection above 3ml/h, set flow rate for 30 minutes for flow rate below 3 ml/h.

5. Optima PT - Technical characteristics

5.1. Mains power supply

Mains supply	100-240 V ~ / 50-60 Hz
Maxi. power consumption	50 VA
Internal protective fuse	630 mAT

5.2. Battery

Characteristics	6 V ⎓ 2.7/3 Ah - NiMH
Battery life	4 h min for any flow rate lower than 125 ml/h
Battery recharging	Device off: 5 hours / Device on: 16 hours

5.3. Compliance

Compliance with EN 60 601-1 and EN 60 601-2-24.

CE 0459	CE 0459 marking in compliance with EEC 93/42 Medical Device directive
IP31	Protection against splashing fluid
	Protection against leakage current: Type CF equipment
Class I	Protection against electric shocks
	Functional earth
	Equipotentiality
	dc voltage

5.4. Device materials : all components are Latex free

Housing	Polycarbonate, ABS
Keyboard & labels	Polyester
Pumping track membrane	EPDM Elastomer
Drip sensor	Polycarbonate

5.5. Dimensions - Weight

Height / Width / Depth	13.5 x 17.5 x 14.5 cm
Weight	approx. 2.9 Kg

5.6. Symbols

	The operator's guide should be completely read prior to use the device
	Battery
	Fuse
	Drip sensor inlet
	Nurse call connection
RS232	RS 232 outlet

5.7. Indicators lights

Mains power operation		yellow
Battery power operation		green
Infusion in progress		green
Confirm signal		green
Pre-alarm		orange
Alarm		red
Flow rate	125	green
Drop		Green
LCD		Black, backlighted

5.8. Electronic retainer memory

In case of prolonged switched off, all parameters of the device are stored indefinitely except for the date which is lost after 3 months storage. When the pump is switched ON, settings of the new date are proposed.

5.9. Data log event

The last 764 dated events are stored and can be read with the maintenance software.

5.10. Curves

Trumpet curves demonstrate the evolution of the minimum and maximum variance of the PUMP / SET combination versus flow rate.

The test protocol used to obtain these results is described in the EN 60 601-2-24. For further information, please refer to this publication. Use these curves to determine the accuracy depending upon your infusion protocol / drug / dilution.

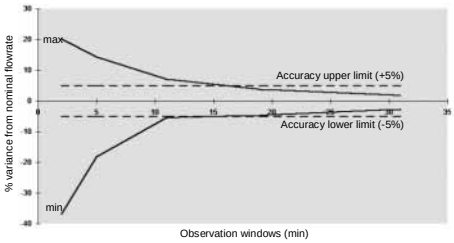
Sequential and Ramp up / down curves are given for a typical representative programming protocol parameters:

- **Sequential: 40 ml/h for 10 ml, 100 ml/h for 30 ml, 5 ml/h for 1.5 ml, 40 ml/h for 6 ml.**
- **Ramp up / down: Ramp up time setting: 15 minutes, Ramp down time setting: 15 minutes, Stabilised flow rate: 115 ml/h, Total volume to be infused: 70 ml.**

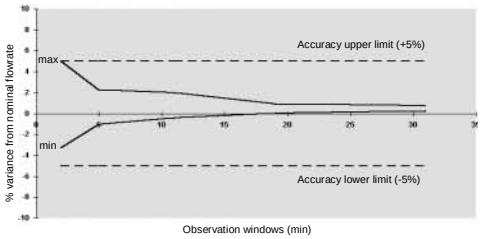
These graphs are therefore representative of VS PVC type sets during trials and serve as an indication only of the pump's overall performance. Please contact our after-sales department for other curves.

5.10.1. Trumpet curves for 2, 5, 11, 19, 31 minutes observation windows

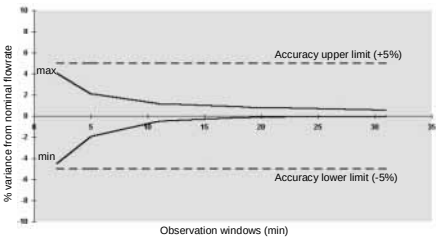
1 ml / hour:



25 ml / hour:



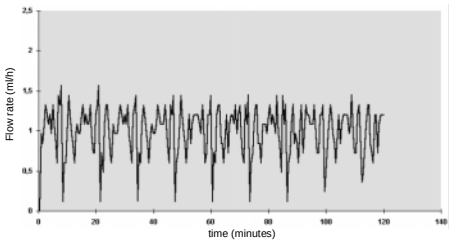
100 ml / hour:



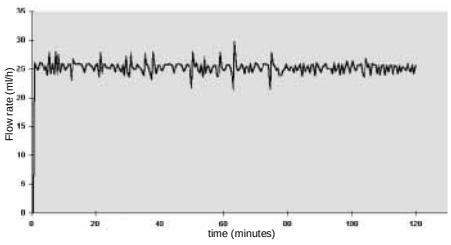
5.10.2. Flow rate / time curves: start-up and instantaneous flow rate

(in ml/h, measured every 30") versus time (in second).

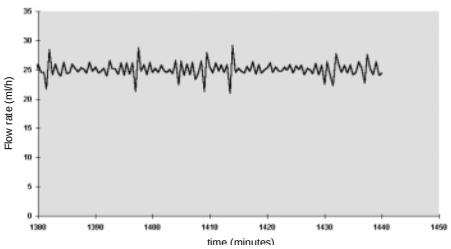
1 ml / hour:



25 ml / hour:

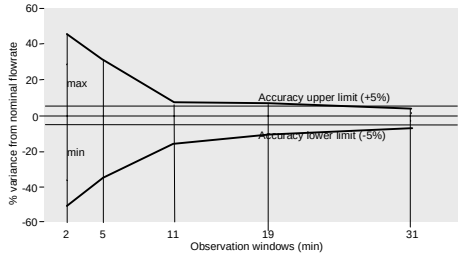


100 ml / hour:

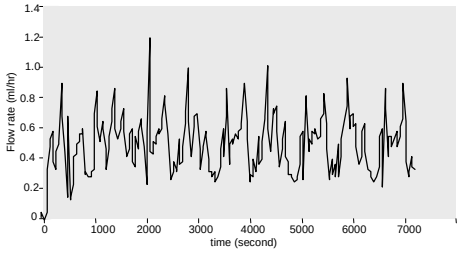


5.10.3. Curves for micro infusion mode

Trumpet curves at 0.5 ml / hour:

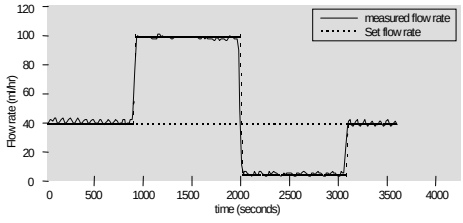


Instantaneous flow rate at 0,5 ml / hour:

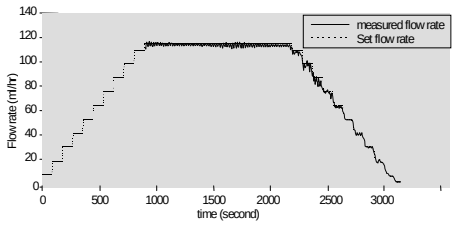


5.10.4. Flow rate / time curves: sequential mode, ramp up / ramp down mode

40 ml/h for 10 ml, 100 ml/h for 30 ml, 5 ml/h for 1.5 ml, 40 ml/h for 6 ml



Ramp up : 15', Ramp down : 15', Stabilised flow rate : 115 ml/h, Total vol. : 70 ml.



6. Configuration menu

Fresenius Vial **recommends the presence of its qualified personnel or a member of the Technical Department of your establishment to help you implement the configuration procedures you wish to choose.**

Note: press STOP to cancel modification at any time - Press OFF % to leave configuration mode at any time.

6.1. Access to the configuration menu

1. To access configuration menu, press % key. Then, keep MODE key pressed.
2. Select required item with ⏫🔼🔽⏬, and enter in required item by pressing START.

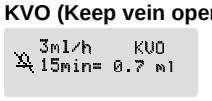
Note: Maintenance setting is accessible by Bio Medical Technicians. Please refer to the Technical Manual.

6.2. "User setting " menu

Infusion modes

1. Select required item with ⏫⏬ and activate with a tick or de-activate required item by pressing 🔼🔽.
   All infusion modes with a tick will be proposed when switching the pump on.
   Micro-infusion mode: display of one decimal from 0,5 ml/h to 99,9 ml/h.
   Setting with flow rate only: infusion with no volume limit and no time limit
   (end of infusion when empty container is detected by drop detector).
   Ramp-up / Ramp down: progressive increase and decrease of flow rate.
   Sequential infusion: programming of 1 to 20 infusion sequences automatically linked together.
   Loading dose: infusion of a loading dose prior to primary infusion.
   Bolus: infusion of a bolus before or during a primary infusion.
   Secondary infusion: infusion of a secondary line followed by the primary infusion.
   Lock function: enables the locking of key board after the infusion has been set.
2. Confirm setting by pressing START.

KVO (Keep vein open)

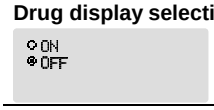


1. Select KVO rate from 0 (no KVO) to 20 ml/h. Then, shift to next item with ↵ increment 1 ml/h.
2. Select silence alarm duration during KVO from 2 to 30 minutes.
3. Confirm setting by pressing START.

Pressure setting

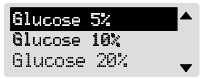
1. Select pressure threshold from 100 to 900 mmHg with ⏫🔼🔽⏬. This threshold will be proposed when switching the pump on. Shift to next item with ↵.
   mmHg recall of the last pressure threshold when the pump is switched on.
2. Select pressure drop threshold from 100 to 500 mmHg with ⏫🔼🔽⏬.
3. Confirm setting by pressing START.

Drug display selection



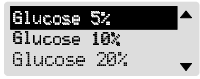
1. Select by pressing ⏫🔼🔽⏬ whether you wish the drug name to be displayed.
2. Confirm setting by pressing START.

Primary drug list



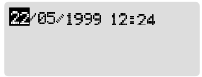
1. Select required drug name with ⏫⏬. Then, activate with a tick or de-activate required drug name by pressing 🔼🔽. All drug names with a tick will be proposed in primary drug list.
2. Confirm setting by pressing START.

Secondary drug list



1. Select required drug name with ⏫⏬. Then, activate with a tick or de-activate required drug name by pressing 🔼🔽. All drug names with a tick will be proposed in secondary drug list.
2. Confirm setting by pressing START.

Time setting



1. Select value by pressing ⏫🔼🔽⏬. Then, shift to next item with ↵.
2. Confirm setting by pressing START.

Language

1. Select desired language by pressing ⏫🔼🔽⏬.
2. Confirm setting by pressing START.

LCD contrast

1. Increase contrast by pressing 🔼 or decrease contrast by pressing 🔽.
2. Confirm setting by pressing START.

6.3. Ward setting

Ward setting

1. Enter code with ⏫🔼🔽⏬, and confirm by pressing START (pre-set code is 200).
2. Select required item with ⏫🔼🔽⏬ and enter the required item by pressing START.

Ward name

1. Select desired letter with 🔼🔽. Shift to next letter with ↵.
2. Confirm setting by pressing START.

User code

The user code is settable from 0000 to 9999. If user code is set at 0, the user setting menu is then accessible without code entry.

1. Enter code with ⏫🔼🔽⏬.
2. Confirm setting by pressing START.

Bolus reduction during occlusion release

1. Select by pressing ⏫🔼🔽⏬ whether you wish to activate bolus reduction after release of an occlusion.
2. Confirm setting by pressing START.

Maximum rate

1. Select by pressing ⏫🔼🔽⏬ the maximum flow rate you wish to allow during infusion setting (valid for all infusion modes except bolus and loading dose).
2. Confirm setting by pressing START.

Air bubble size

1st parameter: cumulated air volume over a period of 15 minutes after which the air bubble alarm will trigger: select value from 30 to 1000 µl with ⏫🔼🔽⏬. Shift to next item with ↵.
Note: a continuous air bubble greater or equal to the cumulated programmed volume will trigger an alarm independent from the time period.
2nd parameter: minimum air bubble size you wish to take into account within the cumulated air volume over 18 minutes.
Select value from 10 to 200 µl with ⏫🔼🔽⏬. If 1 is selected, all detectable bubbles will be taken into account.

1. Confirm setting by pressing START.

Fixed initial parameters

Select by pressing ⏫🔼🔽⏬ whether you wish to fix infusion parameters (rate, volume, drug name…) for all infusion modes :

- ON : when switching the pump on, the same parameters are always proposed.
- OFF : when switching the pump on, the last set parameters are proposed.

Volume screen

Select by pressing ⏫🔼🔽⏬ whether you wish to display the volume screen :

- ON : display of the volume screen during infusion.
- OFF : display of the infusion setting during infusion.

Infused volume stored at power off

Select by pressing ⏫🔼🔽⏬ whether you wish the last infused volume to be recalled when switching the pump on :

- ON : recall of the last volume (enabling cumulating).
- OFF : total volume infused is pre-set at 0.

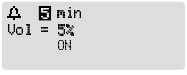
Keep interrupted program for

Select by pressing ⏫🔼🔽⏬ the time you wish the last infusion parameters to be recalled when switching the pump OFF then ON. From 0 h 15 to 24 h 00.
If 0 h 00 is selected, parameters are not recalled.

Infusion modes transition

Select required item with⏫🔽. Activate with a tick or de-activate required item by pressing 🔼🔽 whether you wish 3 beeps to be triggered after advanced infusion mode.

Pre-Alarm



Select required item with ↵, adjust value by pressing ⏫🔼🔽⏬, Confirm setting by pressing START.

1. Remaining infusion time which triggers an end of infusion pre-alarm : from 5 to 30 minutes.
1. Remaining volume to infuse (in % of total volume to infuse) which triggers an end of infusion pre-alarm from 0 to 15%.
   - ON : end of infusion pre-alarm is always activated when the first above condition is reached.
   - OFF : end of infusion pre-alarm not activated.

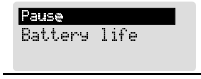
Buzzers

Select by pressing ⏫🔼🔽⏬ the type of buzzer type 1 or type 2.

Automatic ON

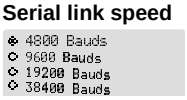
Select by pressing ⏫🔼🔽⏬ the activation of automatic switch ON at door opening (when connected to mains).

Screen with Mode key



Select by pressing 🔼🔽 the items which can be reached from the Mode key in the menu : Pause, Battery life.
⏫🔽 allows you to shift from an item to another.

Serial link speed



Select by pressing 🔼🔽 the serial link speed.

7. Precautions to be taken

The symbol ⚠, visible inside door label of the device, recommends this Operator's Guide should be completely read in accordance with the EN 60 601-1 Standard.

***Fresenius Vial* will not be liable for any damages or claims, medical or otherwise, of any nature whatsoever, whether direct or consequential, caused by improper use of this device.**

In order to insure that all the safety features of the device are activated, the pump should be switched ON prior to being connected to the patient.

Special attention must be paid to the stability of the device. Use the device in horizontal position, on a table, or with the incorporated clamp for using on a pole.

Fresenius Vial recommends not to place the pump higher than 1,3 metre above patient.

Container must be placed on a range of 50 cm above the pump ± 30 cm.

During all manipulations on the pump or on the set (set installation, door opening, set removal), make sure the line is closed near to the injection device with a clamp or a stopcock. If they are not available, we recommend a back check valve to be assembled on the injection device in order to avoid any pressure variations which may occur due to the compliance of the line.

Recommendations to improve performances and safety when the pump is commonly used at low flow rates (≤ 20 ml/h) :

- Limit the range of available flow rates in accordance with the maximum flow rate to be used with your protocol (see configuration menu);
- The time to detect a downstream occlusion being conversely proportional to the flow rate, it is recommended to lower the pressure limit in order to gain in time to detect an occlusion.

For the infusion of very short half life drugs at flow rate below 5 ml/h, we recommend the use of syringe pumps which usually offer better performances of instant flow rates. Check instant flow rate curves and trumpet curves.

We recommend you partially or completely recharge the battery when you receive the device or in the case of prolonged storage so as to prevent all risks of premature discharge.

To preserve the environment, remove the battery from the device prior to destruction or at the end of the device life and as during normal maintenance replacement, return it to a competent recycling organisation. Proceed in the same way for the device itself (electronic boards, plastics…).

Avoid short circuit and excessive temperature.

Anaesthetic substances: the device must not be used in the presence of inflammable anaesthetic agents due to the risk of explosion. It should always be used away from all risk areas.

The device is designed to infuse any medical substance that can be injected in normal conditions of temperature: +18°/+30°C. The physiological effects of medicine can be influenced by the characteristics of the device and the associated disposable (constitution material is commonly listed on the set packaging). Check that they are compatible with prescriptions, the characteristics of trumpet curves and occlusion alarm setting times in relation to the programmed flow rate.

When using the pump with protocols including refrigerated solution, check normal temperature of the solution container (+18°/+30°C) before the installation of the infusion set into the pumping system. This medical device complies with IEC 60 601-2-24 for environmental range of use (+ 5°C to + 40°C, 20% to 90% relative humidity) but due to the range limitation condition of the solution to be infused, we recommend a normal use condition from + 18°C to + 30°C.

Use only disposable proposed in this Operator's Guide in accordance with local standard operating procedures and good clinical practices. Using non recommended disposable could lead to serious hazards such as free flow or pump degradation.

After the disposable is primed, check the integrity of the connected disposable to patient (no leak, no air, especially after the air bubble sensor).

Fuses should be replaced by equivalent parts. This should be done by a qualified technician. Refer to the part list of the technical manual for full specification.

The pump may only be connected to the mains with the power cord supplied by the manufacturer. Check that the mains voltage corresponds with the value indicated on the label placed underneath the device.

Do not exceed the permitted voltage on the different external connections.

The settings parameters which have been modified but not validated by the users, or the ones which are proposed after the pump has been switched on may trigger an alarm after a while. The default values which are then proposed by the pump may vary according to ongoing status (Start-up, Stop, Infusion). In any case, check the setting parameters are in accordance with the one you wish.

This device can be disturbed by a strong electromagnetic fields, external electrical influences and electrostatic discharges above the limits stipulated by EN 60 601-1-2 and EN 60 601-2-24 (e.g.: mobile phones, surgical equipment leads close to the pump). It can also be disturbed by environmental pressure or pressure variations, mechanical shocks, heat ignition sources, etc.

Standard precautions should be taken to prevent contamination or injuries while discarding the associate waste disposables (e.g. extension sets, etc.).

High inline depression may create free flow.

Only use luer lock connection to prevent disconnection due to infusion pressure.

Make sure that all connection tubes and other infusion devices, that may be connected to this pump, will resist to a pressure up to 2000 HPa.

Do not use in conjunction with positive pressure infusion devices, that could generate backpressure higher than 1500 HPa, susceptible to damage infusion disposables and the device (e.g. contrast fluid devices).

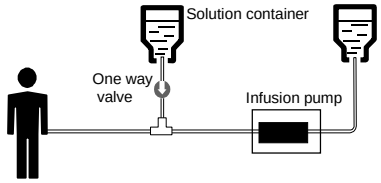
While in use, negative pressure variation may occur in the line, by the relative height from the device to the injection site or by combination with pumping devices such as blood pump, alternative clamp, etc.

Pressure variation may generate flow rates fluctuation mainly noticeable at low flow rates.

When the reservoir is placed higher than the injection site, please pay attention to manipulate the set only when it is clamped or disconnected from patient side.

Make sure that infusion line does not hinder moving parts of other devices.

Fresenius Vial recommends the use of one way valves or positive pressure infusion devices for multi-line infusions. If there is no one way valve on a gravity infusion line during a multi-line infusion, this will make it impossible to detect occlusions on the patient side, and could result in accumulation of the drug being infused in the gravity line, which could later be infused in an uncontrolled manner when the occlusion is released. Place the connection between the gravity line and the pump-driver line as near to the start of the set as possible in order to minimise the dead space and consequently the impact of any change in flow rate on the gravity line.



All computer systems connected to the RS 232 link on the base must meet the safety features, as in the IEC 950 standard for computer interfaces.

Fresenius Vial will not be responsible whatsoever for use of any interface communication between the Optima pump and computer systems.

Opening the pump or the battery cover must only be carried out by the qualified personnel in your establishment, and taking all the necessary technical precautions. Non-respect of these procedures is dangerous to the personnel and may damage the pump. We recommend you follow the maintenance procedures defined in the Technical Manual. To obtain a copy of the Technical Manual, please contact our After-Sales Department specifying the identification number of the device.

8. Maintenance recommendations

8.1. Cleaning and disinfection

The device forms part of the patient's immediate environment. It is advisable to clean and disinfect the device's external surfaces on a daily basis in order to protect patient and staff.

- Disconnect the device from its mains supply before starting to clean.
- Do not place in an AUTOCLAVE nor IMMERSE the device. Do not let fluids enter the device's casing.
- If the device is placed in a high contamination risk unit, it is advisable to leave it in the room during aerial disinfection, after having disinfected it with a moist cloth.
- Use a cloth soaked in DETERGENT-DISINFECTANT, previously diluted with water if required, to destroy micro-organisms. Avoid abrasive scrubbing which could scratch the casing. Do not rinse or wipe surfaces.
- Do not use: TRICHLOROETHYLENE-DICHLOROETHYLENE - AMMONIA - AMMONIUM CHLORIDE - CHLORINE and AROMATIC HYDROCARBON - ETHYLENE DICHLORIDE-METHYLENE CHLORIDE - CETONE. These aggressive agents could damage the plastic parts and cause device malfunction.
- Take care also with ALCOHOL BASED SPRAYS (20% - 40% alcohol). They lead to tarnishing of and small cracks in the plastic, and do not provide the necessary cleaning prior to disinfection. Using disinfecting applies by SPRAYS may be done, in accordance with the manufacturer recommendation, from a distance of 30 cm of the device, avoid the accumulation of the product in fluid form.

Please contact the appropriate service, handling suitable cleaning and disinfection products, in your establishment for further details.

8.2. Storage

The device should be stored in a dry, cool place. In case of prolonged storage, the battery should be disconnected. This should be done by a qualified technician.

- Permissive relative humidity: from 20% to 90%, no condensation.
- Storage temperature: -10°C + 60°C.

8.3. Servicing

To ensure normal performance of the device, it is recommended to replace the internal battery every 3 years. This should be done by a qualified technician.

The qualified technicians in your establishment or our After-Sales Department should be informed if the device is dropped or if any malfunction occurs. In this case the instrument must not be used. For further information please contact our After-Sales Department.

If the device has to be returned to our After-Sales Department, proceed to its cleaning and disinfection. Then, pack it very carefully, if possible in its original packaging, before shipping.

Fresenius Vial is not liable for loss or damage to the device during transport to our After-Sales Department.

8.4. Regular inspections

In order to insure that the device is functioning optimally, regular inspections of the device are recommended every 12 months.

A regular control check consists of various inspection operations listed in the Technical manual. These control checks must be performed by an experienced technician. There are not covered by any contract or agreement provided by ***Fresenius Vial*** and are under the responsibility of the User.

Note: failure to comply with these maintenance procedures can damage the device and lead to a functional failure.

9. RS 232 connection

RS232

The installation as well as the use of the infusion pump via a RS 232 interface must be in compliance with the installation protocol described in the Technical Manual of the device.

For further information, please contact our After-Sales Department.

10. Nurse call connection

The nurse call connection, situated on the back of the pump, enables the connection of the device to a nurse call.

For further information, please contact our After-Sales Department.

11. Drip sensor

1. Connect the drop detector plug of to the connection socket on the back of the pump.
2. Connect the drop detector to the drip chamber.

Important: control the right positioning of the drip chamber and check there are no drops on the drip chamber walls.

12. Function with the internal battery

The device contains an internal battery which automatically takes over when the mains supply is disconnected and ensures normal function with no loss of the programmed data.

Operation from the battery is visualised by the battery indicator .

12.1. Recharging the battery

To recharge battery, just connect the pump to a mains power supply. Recharging of the battery is visualised by the mains indicator .

12.2. Recommendations

The battery should be replaced every 3 years or according your local servicing recommendations.

The loading charge indicator may be affected (lower battery life) if the battery is out of order or too old.

13. Accessories

Fresenius Vial recommends the use of Optima PT range accessories.

Rolling stand 180 - Cat # 073070

High stability rolling stand - Height 1.80 m - 5 rollers - Burnished pole.

Cast iron - Cat # 073074

Added to high stability rolling stand 180, for live loads higher than 16 kg.

Transrail 120 - Cat # 073071

Two clamps which firmly fix a burnished pole on 2 parallel rails.

14. Disposable

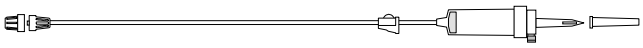
14.1. VS range

In order to use the Optima PT pump in best conditions and cover most applications, we have developed a complete range of sterile disposables: the VS series.

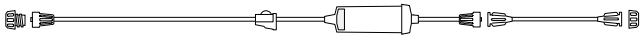
Due to the quality and diversity of this range, you are offered a selection of high performance administration sets.

Designation

VS 10 - Infusion set with 15 µ filter - L ~ 240 cm

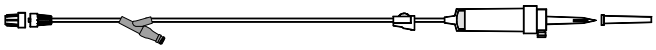


VS 20 - Infusion set with 100 µ filter and male or female luer lock - L ~ 250 cm

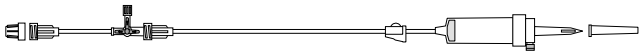


VS 30 - Infusion set with injection site (Latex free) and 15 µ filter - L ~ 250 cm

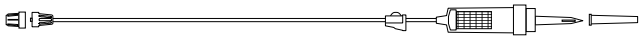
VS 31 - Infusion set for infusion, with 15 µ filter and needle-free access for intermittent injection - L ~ 240 cm



VS 33 - Infusion set with 15 µ filter and 3-way stopcock for injection of medicines - L ~ 250 cm



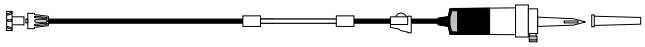
VS 50 - Infusion set with 200 µ filter for transfusion - L ~ 240 cm



VS 60 - Infusion set with 15 µ filter for infusion of drugs non compatible with PVC - L ~ 250 cm

VS 70 - Infusion set with 15 µ filter and 0.22 µ antibacterial filter for infusion of drugs non compatible with PVC (Taxol) - L ~ 250 cm

OP VS - Opaque infusion set for infusion of light sensible drugs, with 15 µ filter - L ~ 265 cm



All sets are designed and controlled by Fresenius Vial in order to guarantee the performances and the safety features of our pump. The manufacturing is done by Fresenius Vial (CE0459) or by its qualified subcontractors (CE0123, CE0318) for and on behalf of Fresenius Vial in exclusive distribution. The CE certificates are available on request.

Notes:

- **These sterile infusion sets are packed in an individual peeling pouch by carton of 100 units.**
- **These sets are single use.**
- ***Fresenius Vial* is not responsible for the use of Optima PT pump with non-recommended sets.**

14.2. Other PVC giving sets

Fresenius Vial recommends the use of the following sets :

- MCM400 infusion set (Fresenius MCM)
- VS XX sets (Fresenius Vial)
- Fresenius Infudrop Air PD
- Codan PVC (Pressure)
- Braun Intrafix
- BD Ohmeda R 87 P

The choice of the set to be used with the pump should be selected in the Configuration menu : Maintenance / Configuration / SAV2 Set selection.

MCM400 infusion set and VS XX set ranges are made of bio-compatible plastic materials

Single use, with 5 year shelf life.

MCM400 & VS XX infusion sets with different filter sizes.

Note : the staff of the hospital should check the compatibility of the fluid or drug to deliver with the components listed on the pouch: materials, filter size, special recommendations.

All Fresenius Vial sets are designed and controlled by Fresenius Vial in order to guarantee the performances and the safety features of our pump. The manufacturing is done by Fresenius Vial (CE0459) or by its qualified subcontractors (CE0123, CE0318) for and on behalf of Fresenius Vial in exclusive distribution. The CE certificates are available on request.

15. Conditions of guarantee

Fresenius Vial **guarantee that this product is free from defects in materials and workmanship (excluding batteries and accessories) for a period of one year from the date of invoice. If you comply to benefit from the materials and workmanship guarantee from our After-Sales Service or an agent authorised by *Fresenius Vial*, the following conditions must be respected:**

- The device must have been used according to the instructions in this Operator's Guide.
- The device must not have been damaged when in storage, at the time of repair, or show signs of improper handling.
- The device must not have been altered or repaired by non-qualified personnel.
- The serial number (ID/N°) must not have been altered, changed, or erased.

In case of non-respect of these conditions, ***Fresenius Vial*** will prepare an estimate for repair covering the parts and labour required.

Where return and repair of a device is necessary, please contact ***Fresenius Vial*** Customer or After-Sales Department.

Notes

Notes

16. Useful addresses

All requests for information or documentation (technical files, tubing sets catalogue or brochures) must be sent to:

CUSTOMER SERVICE - AFTER-SALES SERVICE:

Fresenius Vial
Le Grand Chemin
F-38590 BREZINS (France)

Tel: +33 (0)4 76 67 10 10
Fax: +33 (0)4 76 67 11 34

E-mail: customers.vial@fresenius-hemocare.com

Consult our Web site
www.fresenius-vial.fr

This document may contain inaccuracies or typographical errors.
Modifications may thus be made and will be included in later editions.

As standards and equipment change from time to time, the features shown and described in this document must be confirmed by our departments.

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Fresenius Vial - Le Grand Chemin - F-38590 BREZINS (FRANCE)